OECD Draft Guidelines on Biobanks

MEMORANDUM FROM THE ARTS AND HUMANITIES RESEARCH COUNCIL TO THE ORGANISATION FOR ECONOMIC CO-ORDINATION AND DEVELOPMENTS CONSULTATION ON THE DRAFT GUIDELINES FOR HUMAN BIOBANKS AND GENETIC RESEARCH DATABASES

The Arts and Humanities Research Council (AHRC) welcomes this opportunity to respond to the OECD's consultation. This response does not include or necessarily reflect the views of the Science and Innovation Group in the Department for Innovation, Universities and Skills of the British Government (who fund the AHRC and other UK research councils).

The AHRC supports research in the UK within a huge subject domain from traditional humanities subjects, such as history, modern languages and English literature, to the creative and performing arts. The AHRC funds research and postgraduate study within the UK's higher education institutions. In addition, on behalf of the Higher Education Funding Council for England, it provides funding for museums, galleries and collections that are based in, or attached to, higher education institutions in England.

The information in this response comes from two sources :

1) Dr Sabina Leonelli, Philosopher of Science, ESRC Centre for Genomics and Society, University of Exeter.

2) Professor Graeme Laurie, Director of the AHRC Research Centre for Studies in Intellectual Property and Technology Law at the University of Edinburgh

Introduction

The guidelines in their present form address mainly the relation between HBGRDs and participants. The regulation of the relation of each HBGRD to other HBGRDs, as well as the relation between HBGRDs and the end-users, are given less emphasis. Even when such relations are clearly implied in the guidelines (e.g. Annotations 17, 21), it is felt that they should be given more prominence to ensure long-term collaboration and communication among HBGRDs and between HBGRDs and their users.

Each HBGRD should be explicitly encouraged to use common (where possible, internationally established) standards for the storage and retrieval of data and materials, or at least to collaborate as extensively as possible with other HBGRDs to this aim. This fosters the efficient re-use of data and materials by end-users; the avoidance of needless duplication of efforts (both by end-users and by HBGRD staff); and the establishment of links between HBGRDs (which facilitate consultation and comparison of results from multiple HBGRDs at the same time, which is often required by users).

Asking HBGRDs to follow international standards does not address the frequent cases where standards have not yet been set. Also, it does not encourage collaboration among HBGRDs.

Suggestions and comments

It is therefore suggested that the guidelines encourage consultations between HBGRD curators, as well as consultations between curators and end-users, from the moment of its creation to the moment of its eventual termination. When establishing a HBGRD, a mechanism should be devised for the *uptake of criticism* from curators working in other HBGRDs and from end-user groups.

The guidelines specify that HBGRD curators should consult and abide as much as possible to international standards (e.g. 6.E). This indication is however insufficient, as in several cases there is no international body responsible for establishing standards and there is no agreement yet among HBGRDs on what should be accepted as common standard.[1]

Also, the guidelines do not suggest that HBGRD curators should hold regular consultations with their users to determine the quality and usefulness of their services to biomedical research. It is recommended that HBGRDs implement a mechanism for gathering feedback from their user communities *as well as* for addressing whichever critique or demand they receive from users.

These suggestions and comments are relevant especially to the following points (*suggested modifications in italics*):

1. HBGRDs Generally

1.A Should the objective be limited to health-related research?

1.3 and 1.5 are both concerned with privacy; how do they differ?

2. Establishment of HBGRDs

Should governance provisions not be considered in tandem with the development of the protocol and establishment of the HBGRD? It is recommended that consideration is given to the example of UK BIOBANK in this regard.

2.B In the establishment of the HBGRD, the initiators should carry out consultations with stakeholders and the general public. *Stakeholders include participants, curators and other HBGRD staff, prospective user groups, staff from other HBGRDs and*

[1] For instance, for several types of data there is no international agreement on a preferred format. Projects who try to establish standards for data formatting are few and badly funded, only occasionally rising to the challenge of supplying a successful standard (see Taylor CF et al (2007) The minimum information about a proteomics experiment (MIAPE). *Nature Biotechnology* 25, 887 – 893).

advisors from relevant international bodies (concerning legal and financial regulations as well as scientific and technical standards).

+ [to be added] *The HBGRD should develop a strategy for uptake of criticism and suggestions from stakeholders and the public.*

2.1 It is suggested that this section reflect the phrasing of 2B and speak of participants, stakeholders and the general public.

2.10 Is representativeness desirable in scientific or other terms?

3. Governance, Management, and Oversight

3.C Surely this should only be the case if a conflict arises? In all other cases, a balance of interests should be sought.

3.G Should this include specific mention of lay or non-expert persons?

3.I Should these means be publicly available?

3.6 By reference to what should these matters be considered?

3.8 and 3.9 What will count as significant?

4. **Terms of Participation**

4.B Does the substitute only apply when principal person is incapacitated as opposed to unavailable or uncontactable?

4.2 Is the intention here that consent should always be sought as the preferred approach or can authorisation be preferred? (this is an important point of principle and practicality).

5. **Contents of HBGRDs**

5.B and 5.3 The former seems to say that consent should always be sought but the latter suggests authorisation can be equally valid. Would this not also apply in the case envisioned by 5.B?

5.4 and 5.5 It is suggested that these points would benefit from further clarification in terms of both expression and scope.

5.G + [to be added] *The development of such procedures and policies should be in consultation with staff at other HBGRDs and with stakeholders, particularly prospective end-users who need to be able to access specimens and/or data in the easiest possible ways.*

6. Protection of Human Biological Materials and Data

Is there a role to mention ISO security standards here as best practice?

6.E + [to be added] *In the cases where such internationally-accepted technological standards and norms do not yet exist, HBGRD staff should seek consultation with as many other relevant stakeholders as possible to develop widely accepted standards. HBGRD staff should also actively participate in international efforts to achieve such standards in the future.*

7. Access

Policies should be public and written in accessible language for all readerships, especially participants and future users.

Policy should be available for participants at time of original consent.

Should negative results not also be fed back to the HBGRD?

Should independent access committees handle requests for access? There is a need to assess scientific validity *and* impact on participant interests.

9. Custodianship, Benefit-sharing and Intellectual Property

9.3 + [to be added] *Such policy should be developed in consultation with all stakeholders, particularly end-users and other HBGRDs initiators.*

10. Demise of the HBGRD and Disposal of Materials and Data

10.F and 10.2 There is concern as to whether these two points are consistent with each other.